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NOTES

BUILDING A BETTER MOUSE — AND PATENTING IT. ALTERING THE PATENT LAW TO ACCOMMODATE MULTICELLULAR ORGANISMS

As a result of advances in the field of biotechnology, researchers develop unique, nonnaturally occurring multicellular organisms. These researchers desire patent protection for their living inventions. However, the patent laws of the United States do not adequately provide for the patenting of multicellular organisms. Furthermore, proposals to amend the patent laws are insufficient. The author analyzes current patent law and existing proposals to amend that law. The author then proposes an amendment to the patent laws to better accommodate living organisms. The proposed legislation includes a clear definition of patentable life-forms, a depository requirement, a farmer's exemption, and a researcher's exemption.

INVENTORS HAVE TRADITIONALLY labored to build a better mousetrap. More recently, however, their focus has changed; through advances in the science of biotechnology,¹ inventors now labor to build better mice, cows, pigs, and many other multicellular organisms.² The developers of these living inventions,

1. Biotechnology is defined as "any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop microorganisms for specific uses." OFFICE OF TECHNOLOGY ASSESSMENT, PUB. NO. 5, 101st Cong., 1st Sess., NEW DEVELOPMENTS IN BIOTECHNOLOGY: PATENTING LIFE 3 (1989) [hereinafter PATENTING LIFE] (special report).

2. See *Patents, House Panel Hears Testimony Addressing Animal Patenting Issues*, Daily Rep. Exec. (BNA) No. 184, at A-6 (Sept. 25, 1989) [hereinafter *Patents*] (statement of Kevin W. O'Connor, Office of Technology Assistance) ("Animals that are useful

like the creators of inanimate inventions, seek to protect their discoveries through the patent laws.³ In fact, over seventy-five patents on multicellular organisms are currently pending at the United States Patent and Trademark Office ("Patent Office").⁴ Although the patenting of micro-organisms has been an accepted practice for several years,⁵ multicellular organisms only recently have been found to be patentable subject matter.⁶ Congress, how-

in research, particularly mice, will likely be developed first and subsequent research will focus on cattle, swine, goats, sheep, poultry and fish."); Kaplan, *Firms Seek Royalties for Patented Animals*, Newsday, Oct. 29, 1989, at 62, col. 1 ("[M]ore than a dozen entrepreneurial companies are in the late stages of developing lab animals for biomedical research, improved livestock and animals that can secrete valuable pharmaceutical proteins in their milk.").

3. See Ihnen, *Patenting Biotechnology: A Practical Approach*, 11 RUTGERS COMPUTER & TECH. L.J. 407, 407-08 (1985) ("At the present time patent protection is preferred to trade secret protection for biotechnology."). Patent law protection is preferred for several reasons: start up companies need tangible assets to raise capital; companies need protection of their particular areas of expertise in order to stay in business; the inventions are easily reproducible so the compromise of a small sample can result in the loss of a trade secret; and granting patent rights engenders competition which spurs new innovations. *Id.* at 408 n.6.

4. 135 CONG. REC. E3008 (daily ed. Sept. 12, 1989) (statement of Rep. Cardin). The Patent Office often deals with inventions in biotechnology despite issuing relatively few patents for multicellular organisms. Between 1983 and 1987, the Patent Office issued 5,916 patents for inventions in the area of biotechnology. See PATENTING LIFE, *supra* note 1, at 29 (table 2-1). Approximately "6,900 biotechnology patent applications were pending as of January 1988." *Id.* at 29. To keep pace with the large number of biotechnology patent applications being filed, the Patent Office has created "a new patent examining group, Group 180, which consolidated into a single group all of the various arts which comprise biotechnology." Establishment and Solicitation for Board Members for the Biotechnology Institute, 54 Fed. Reg. 7,580 (1989) (supplementary information to comments of Patent Office).

5. See, e.g., *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) (genetically engineered micro-organisms can be patented under the U.S. patent statutes). Micro-organisms are "[m]inute, microscopic, or submicroscopic living organisms" including bacteria, mycoplasma, and viruses. PATENTING LIFE, *supra* note 1, at 185.

6. See *Ex parte Allen*, 2 U.S.P.Q.2d (BNA) 1425, 1426 (Bd. Patent App. & Interference 1987) (holding that polyploid oysters are nonnaturally occurring "man-made life forms" and therefore patentable); Quigg, *Animals-Patentability*, 69 J. PAT. OFF. SOC'Y 328, 328 (1987) (Donald J. Quigg, Assistant Secretary and Commissioner of Patents and Trademarks, announced that "the Patent and Trademark Office [would now examine] claims directed to multicellular living organisms, including animals.").

Multicellular organisms represent further evolution of living cells by "dividing the labor among different types of cells" within a single organism. B. ALBERTS, D. BRAY, T. LEWIS, M. RAFF, K. ROBERTS & J. WATSON, *MOLECULAR BIOLOGY OF THE CELL* 22 (2d ed. 1989). "Multicellular organisms evolved in which cells closely related by ancestry became differentiated from one another, some developing one feature to a high degree, others another, so farming the specialized parts of one great cooperative enterprise." *Id.* (emphasis omitted).

ever, has not yet reacted to this change in practice.⁷

In the wake of its recent decision to accept patent applications for multicellular organisms, the Patent Office faces a number of questions concerning application of the patent statutes to these new inventions. This note argues that Congress should amend the patent statutes to permit the patenting of multicellular organisms. These amendments must address the unique problems posed by patenting living inventions. Part I of this note examines the protective role of the patent system in general and outlines the basic requirements for patenting inventions.⁸ Part II discusses the creation of new multicellular organisms and the subsequent legal and administrative decisions affecting the patentability of these inventions.⁹ Part III briefly discusses the ethical and moral questions raised by the patenting of animals¹⁰ and then explores the need to include a depository requirement,¹¹ a family farm exemption,¹² and a research exemption¹³ in any patent law amendment governing the patentability of animals. This section concludes with an analysis of the problems which attend patenting multicellular organisms under the current law and critiques existing proposals for patent law amendments in this area.¹⁴ Part IV integrates the issues identified in Part III into proposed legislation designed to assist Congress in its attempt to draft guidelines for the patent protection of living organisms.¹⁵

I. HISTORY AND REQUIREMENTS OF THE PATENT LAWS

Much of the controversy surrounding the patenting of multicellular organisms arises from the statutory requirements of the patent system. One must, therefore, have a general understanding of the patent system before analyzing the unique problems created within this system by patenting living organisms.

7. For a discussion of proposed legislation, see *infra* text accompanying notes 146-201.

8. See *infra* text accompanying notes 16-34.

9. See *infra* text accompanying notes 35-92.

10. See *infra* text accompanying notes 93-105.

11. See *infra* text accompanying notes 108-35.

12. See *infra* text accompanying notes 136-41.

13. See *infra* text accompanying notes 142-44.

14. See *infra* text accompanying notes 145-201.

15. See *infra* text accompanying notes 202-46.

A. Role of the Patent System

The Constitution grants Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."¹⁶ To achieve this goal, Congress enacted the patent statutes¹⁷ and created the Patent Office to administer them.¹⁸ In turn, the Supreme Court of the United States has consistently upheld Congress' constitutional right to enact and administer patent legislation.¹⁹

The traditional role of the patent system has been to reward inventors for their ingenuity, thus providing "incentives to develop new technologies that in turn create jobs and economic health for the nation."²⁰ A patent grants the inventor²¹ a seventeen year monopoly on an invention.²² Patent owners jealously guard the monopoly, or exclusivity, which their patents create. One observer has noted that "[i]n highly technical societies, patents have become a source of economic power. Corporations fight long and hard with one another to defend their patents, with the loser sometimes driven out of business or severely weakened as a result."²³ Overall, the prospect of obtaining the exclusivity of patent

16. U.S. CONST. art. I, § 8, cl. 8.

17. PATENTING LIFE, *supra* note 1, at 3. See *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974) ("The patent laws promote the 'Progress of Science' by offering a right of exclusion for a limited period as an incentive to inventors."). See generally *Evans v. Eaton*, 16 U.S. (3 Wheat.) 454, 655-70 (1818) (providing a comprehensive history of both the English law that formed the basis of United States patent law and the early United States patent law itself). Modern patent law is codified in 35 U.S.C. §§ 1-376 (1988).

18. See 35 U.S.C. § 1 (1988).

19. See *Graham v. John Deere Co.*, 383 U.S. 1, 5 (1966) (the power of Congress to legislate patents is granted, and limited, by the Constitution); *McClurg v. Kingsland*, 42 U.S. (1 How.) 202, 206 (1843) (Congress' power to amend patent statutes is limited only by property rights in existing patents); see also E. LIPSCOMB, LIPSCOMB'S WALKER ON PATENTS § 2:2 (3d ed. 1984).

20. Note, *Altering Nature's Blueprints for Profits: Patenting Multicellular Animals*, 74 VA. L. REV. 1327, 1328-29 (1988).

21. This note assumes that the inventor, the patent applicant, and the resulting patent owner are the same entity.

22. See 35 U.S.C. § 154 (1988) ("Every patent shall contain a grant to the patentee for the term of seventeen years [A patent conveys] the right to exclude others from making, using, or selling the invention throughout the United States").

23. *Patents and the Constitution: Transgenic Animals: Hearings Before the Subcomm. on Courts, Civil Liberties, and the Administration of Justice of the House Comm. on the Judiciary*, 100th Cong., 1st Sess. 76-77 (1987) [hereinafter *Hearings*] (testimony of Jack Doyle, Director, Environmental Policy Institute).

rights encourages research and development of modern technology²⁴

In exchange for patent protection, an inventor must fully disclose details of the subject invention. Specifically, an inventor must file a complete and exact description of the invention with the Patent Office.²⁵ This description fully discloses the invention and the public has complete access to it.²⁶ Mandatory publication of patented inventions stimulates further invention in related areas.²⁷

The eventual treatment by Congress of multicellular organism patents is uncertain. However, given the profusion of research currently accomplished by scientists despite this uncertainty, it is unlikely that denying patents for living organisms would halt biotechnological research.²⁸ Although the traditional role of the patent system is to reward inventiveness, Congress has excluded certain classes of inventions from patent protection; for example, inventions related to national defense are not patentable.²⁹ Con-

24. "The grant of patent rights has in fact encouraged research and provided useful new products including research into solutions of problems such as those associated with genetic disorders and increasing food yields." *Hearings, supra* note 23, at 21 (statement of Rene D. Tegtmeyer, Assistant Commissioner of Patents); *Cf. Ihnen, supra* note 3, at 408 n.6 (listing reasons why patent protection is appropriate for biotechnological inventions).

25. PATENTING LIFE, *supra* note 1, at 5 ("[A] written patent application [must describe] the invention in full, clear, concise, and exact terms, setting forth the best mode contemplated by the inventor, so as to enable any person skilled in the art of the invention to make and use it.").

26. E. LIPSCOMB, *supra* note 19, at 54 (3d ed. 1984). "Since the printed patents are available to every member of the public, all of the knowledge and scientific and technical information disclosed in these patents is accessible to all inventors, all arts, all trades and all industries." *Id.* at 57.

27. "[O]ther noninfringing improvements may be developed, and so a patent stimulates improvements by competitors who wish to remain in business." *Id.* at 56 (quoting Presentation given at Symposium on Patents by Charles E. Lucke, Head of Mechanical Engineering Department of the School of Engineering of Columbia University (1939)).

28. *Diamond v. Chakrabarty*, 447 U.S. 303, 317 (1980) ("The grant or denial of patents on micro-organisms is not likely to put an end to genetic research [Furthermore,] legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown").

29. Although Congress has seldom acted to prohibit patents on inventions, it has done so "[w]henever publication or disclosure by the grant of a patent on an invention in which the Government has a property interest might be detrimental to the national security" 35 U.S.C. § 181 (1988). For instance, Congress has forbidden the issuance of patents for inventions relating to atomic weapons: "No patent shall hereafter be granted for any invention or discovery which is useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon. Any patent granted for any such invention or discovery is revoked, and just compensation shall be made therefor." 42 U.S.C. § 2181(a) (1988). For an analysis of the purpose of prohibitions based on national security,

gress may respond similarly to multicellular organisms.³⁰

B. Requirements of the Patent Statutes

According to the patent statutes, an applicant must meet three criteria to receive a patent on an invention: usefulness,³¹ novelty,³² and nonobviousness.³³ In addition, an applicant must satisfy the enabling provision. This provision requires that the patent application contain a description of the invention which is sufficiently thorough to allow reproduction by a person "skilled in the art."³⁴

II. HISTORY OF PRODUCING AND PATENTING MULTICELLULAR ORGANISMS

Both the techniques used to produce new types of multicellular organisms and the brief history of patenting these organisms affect the way the patent statutes should be amended to accommodate these inventions. This section therefore discusses the two most prominent techniques of inventing multicellular organisms³⁵

see Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 MD. L. REV. 1051, 1067 (1988) ("the patent system constrains nuclear energy-related inventions," not to discourage inventors from development, but rather to keep developments away from those who would misuse them); Note, *The Evolution of Patentable Compositions of Matter: The United States Patent Office Accepts Genetically Altered Animals as Patentable Subject Matter Under 35 U.S.C. Section 101*, 2 ADMIN. L. J. 309, 327 (1988) (Nuclear weapons are excluded from patent protection because they "offer no industrial or societal benefits" and are "extremely limited in application.").

30. See *Chakrabarty*, 447 U.S. at 317-18 (Congress has power to prohibit patenting of genetically engineered organisms); *Hearings*, *supra* note 23, at 207-08 (comments of Rep. Kastenmeier) ("[I]t is appropriate for the Congress to look at [patenting animals]. After all [Congress] passed the Plant Patent Act, and a Plant Variety Protection Act So, the Congress has acted in new fields of patentability.").

31. 35 U.S.C. § 101 (1988) ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.").

32. *Id.* § 102 (an inventor is entitled to a patent unless the invention is already known or used in this country or is patented or described in a printed publication in this or another country).

33. *Id.* § 103 ("A patent may not be obtained though the invention is not identically disclosed or described if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious to a person having ordinary skill in the art to which said subject matter pertains.").

34. *Id.* § 112.

35. See *infra* text accompanying notes 32-49.

and summarizes the history of patenting the resulting inventions.³⁶

A. Ways of Inventing Multicellular Organisms

1. Classic Breeding Methods

The most familiar method of creating new multicellular organisms is classic breeding. In this technique, the breeding animals are chosen for the specific physical characteristics, such as color, weight, milk production, or speed, that the breeder wants to enhance or pass on to offspring.³⁷ This selection process is called a phenotypic selection system.³⁸ The classic breeding method, however, is highly unpredictable. Because the initial animals are selected on the basis of manifest physical traits rather than specific genetic characteristics, a multitude of variations can result from the breeding.³⁹

2. Transgenic Processes

A second method of inventing multicellular organisms is transgenics.⁴⁰ In the early 1980s, this technique was developed and used to produce new transgenic multicellular organisms.⁴¹ Much of the current research involving transgenic animals is performed on mice,⁴² although some experiments focus on creating new types of cattle, pigs, sheep, poultry, and fish for commercial use.⁴³

36. See *infra* text accompanying notes 50-92.

37. Cooper, *Patent Protection for New Forms of Life*, 38 FED. B.J. 34, 43 n.60 (1979).

38. *Id.*

39. See *id.* at 44 (quoting *Ex parte Schreiner*, 1 BGHSt IIC 136, 141-42 (1969)).

40. Transgenics is the alteration of animals through the addition of DNA (deoxyribonucleic acid) from a source other than parental germplasm to their germplasm. The added DNA is usually removed from a different species of animal or from a human. PATENTING LIFE, *supra* note 1, at 93-94.

41. See *id.* at 94-95.

42. Mice are commonly used for transgenic research because they are warm-blooded and possess many genetic and physiological similarities to humans; they are small and easy to maintain in large numbers at a modest cost; their genetics and physiology are relatively well understood; and they are available in a variety of genetically consistent lines. *Id.* at 95 (table 6-1).

43. "[T]ransgenic animals are expected to have commercial value in three primary areas: agriculture, biomedical research, and the pharmaceutical industry." Dresser, *Ethical and Legal Issues in Patenting New Animal Life*, 28 JURIMETRICS J. 399, 407 (1988). In agriculture transgenic development of more healthy and efficient food producers has great commercial potential. *Id.* at 407-08. Biomedical researchers will be able to use transgenic animals for the study of human disease and treatment. *Id.* at 408. Transgenic

Transgenic animals are produced by a variety of means, the most common of which is microinjection.⁴⁴ In microinjection, highly purified copies of the desired gene are injected directly into a fertilized animal egg which is then implanted into the female.⁴⁵ It is estimated that no more than five percent of the injected eggs will actually develop into transgenic animals.⁴⁶ Microinjection is therefore considered an inefficient and labor intensive method of altering animals.⁴⁷

At present researchers do not understand fully how to direct injected DNA to the appropriate site within the host animal's genetic material.⁴⁸ However, the process is an improvement over classic breeding methods for three reasons: (1) a line of animals possessing the desired trait can be developed in a significantly shorter period of time; (2) the desired trait can be transferred with substantial certainty and unaccompanied by undesirable characteristics; and (3) genes from almost any organism can be inserted into another organism, whereas classic breeding is restricted to closely related species.⁴⁹

B. History of Patenting Multicellular Organisms

1. *Diamond v Chakrabarty*⁵⁰

In *Diamond v Chakrabarty*, the Supreme Court of the United States considered the question of whether a micro-organism is patentable subject matter under the United States patent laws. Chakrabarty, a microbiologist, sought to patent a genetically

animals may provide pharmaceuticals through "molecular farming." This process involves genetically altering animals to produce valuable chemicals which are then used in the manufacture of pharmaceuticals. *Id.* at 408-09. While transgenic animals will likely be produced for agricultural use in the near future, many researchers believe "that it may be 10 years or more before commercial herds or flocks of transgenic livestock are produced." PATENTING LIFE, *supra* note 1, at 98.

44. PATENTING LIFE, *supra* note 1, at 94. Other techniques include "cell fusion, electroporation, [and] retroviral transformation." *Id.*

45. *Id.*

46. *Id.* at 95. One "accomplished laboratory" has a success rate of between 1% and 2%. *Id.* at 96. The number of intervening stages through which the fertilized egg must pass before becoming a transgenic animal accounts for this low rate. Of the fertilized eggs, not all are suitable for injection; of those injected, not all survive; of those which survive injection to be implanted, very few result in live births; and of those born alive, not all are transgenic animals. *Id.*

47. *Id.* at 95.

48. *Id.* at 95-96.

49. *Id.* at 96-97.

50. 447 U.S. 303 (1980).

engineered bacterium which degrades crude oil; a characteristic which makes it extremely valuable for controlling oil spills.⁵¹ The patent examiner denied Chakrabarty's patent claim for the bacteria itself, but allowed his claims for products and processes involving the bacteria.⁵² The examiner denied the bacteria patent, finding that a micro-organism is a "product of nature" which, as a living thing, cannot be patented under 35 U.S.C. § 101.⁵³

The Supreme Court focused its inquiry on whether Chakrabarty's micro-organism was a nonpatentable, naturally-occurring phenomenon or a patentable "manufacture" or "composition of matter."⁵⁴ The majority reasoned that "Congress plainly contemplated that the patent laws would be given wide scope."⁵⁵ However, the Court emphasized that Congress did not intend section 101 to cover every discovery and that the "laws of nature, physical phenomena, and abstract ideas" are not patentable.⁵⁶ The Court distinguished Chakrabarty's micro-organism as being "markedly different" from any micro-organism found in nature and as having "significant utility."⁵⁷ Thus, "[Chakrabarty's] discovery [was] not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101."⁵⁸

The majority rejected the Patent Office's argument that Congress had excluded living organisms from patentability by enacting the Plant Patent Act and the Plant Variety Protection Act.⁵⁹

51. *Id.* at 305 n.2. Until Chakrabarty's invention, biological control of oil spills involved the use of a mixture of several bacteria, each of which would degrade one component of crude oil. The Chakrabarty micro-organism, by breaking down more than one component of crude oil, created a more rapid and efficient way of attacking oil spills. *Id.*

52. *Id.* at 305-06. The examiner issued Chakrabarty patents on an "inoculum" used to float the bacteria to the oil spill and the process used to actually produce the bacteria. *Id.*

53. *Id.* at 306 (citing 35 U.S.C. § 101 (1988)).

54. *Id.* at 307 (citing 35 U.S.C. § 101). The Court did not consider the issues of novelty under 35 U.S.C. § 102 or non-obviousness under 35 U.S.C. § 103. *Chakrabarty*, 447 U.S. at 307 n.5.

55. 447 U.S. at 308.

56. *Id.* at 309.

57. *Id.* at 310.

58. *Id.*

59. *Id.* at 310-11. Essentially, the Patent Office argued that these acts were necessary to create exceptions to Congress' prevailing rule against patenting life-forms. *Id.*

The Plant Patent Act of 1930, 4486, 35 U.S.C. § 161 (1988) provides that "[w]hoever invents or discovers and asexually reproduces any distinct and new variety of plant may obtain a patent therefor, subject to the conditions and requirements of this title." The Plant Variety Protection Act of 1970, 7 U.S.C. § 2402(a) (1988) provides that "[t]he breeder of any novel variety of sexually reproduced plant (other than fungi, bacteria, or

These statutes provided patent protection for specific living organisms only. The Court examined the appropriate legislative history and determined that Congress intended to distinguish products of nature, both living and non-living, from human-made inventions.⁶⁰ The Court further postulated that bacteria were excluded from the Plant Variety Protection Act because Congress approved of either an earlier case which held that bacteria are not plants under the Plant Patent Act⁶¹ or prior patents issued for bacteria.⁶² Thus, neither the Plant Patent Act nor the Plant Variety Protection Act precluded the patenting of Chakrabarty's micro-organism as the result of "human ingenuity and research."⁶³

The Supreme Court also rejected the Patent Office's argument that micro-organisms are not patentable until Congress expressly authorizes such protection.⁶⁴ The Court held that "[a] rule that unanticipated inventions are without protection would conflict with the core concept of the patent law that anticipation undermines patentability."⁶⁵ Further, "Congress employed broad general language in drafting § 101 [of the patent statutes] precisely because [revolutionary] inventions are often unforeseeable."⁶⁶ This liberal statutory interpretation is extremely favorable to inventors who wish to patent multicellular organisms.

All members of the *Chakrabarty* Court agreed that congressional resolution of the life-form patentability issue would be welcome. Chief Justice Burger, writing for the majority, observed:

first generation hybrids) who has so reproduced the variety, or his successor in interest, shall be entitled to plant variety protection therefor "

60. *Chakrabarty*, 447 U.S. at 313. Justice Brennan rejected the majority's interpretation of the Plant Patent Act and the Plant Variety Protection Act. Instead, he took the position that Congress intended to make a specific exception to the general rule that no living organisms are patentable, even if not naturally occurring. *Id.* at 320 (Brennan, J., dissenting). Brennan argued that bacteria are not patentable because they are living organisms which do not fall within the "carefully limited language" of these two Acts. *Id.* at 319.

61. *Id.* at 313-14 (citing *In re Arzberger*, 112 F.2d 834 (1940) (noting that the term "plant" was intended by Congress to be used in its popular sense, and not to be limited to its strict scientific meaning)).

62. *Id.* at 314 n.9 (noting that the Patent Office granted Louis Pasteur a patent on "yeast free from organic germs of disease" in 1873 and granted two living micro-organism patents in 1967 and 1968).

63. *Id.* at 313.

64. *Id.* at 314.

65. *Id.* at 316.

66. *Id.*

The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot. Congress is free to amend § 101 so as to exclude from patent protection organisms produced by genetic engineering. Or it may choose to craft a statute specifically designed for such living things.⁶⁷

Justice Brennan, writing in dissent, favored "leav[ing] to Congress the decisions whether and how far to extend the patent privilege into areas where the common understanding has been that patents are not available."⁶⁸ Thus, both the majority and the dissent in *Chakrabarty* agree that congressional action is warranted.

2. *Ex parte Allen*⁶⁹

The *Chakrabarty* decision spurred growth of the biotechnology industry in the 1980s because it sustained the possibility of patenting micro-organisms.⁷⁰ Inventors seeking patents on multicellular organisms in particular were further encouraged by the decision of the Board of Patent Appeals and Interferences in *Ex parte Allen*. Although the patent in *Allen* was ultimately denied, the Board's reasoning supported the patentability of human-made, multicellular life-forms.

In *Allen*, the applicants sought to patent polyploid oysters which, because of their sterility, do not use their body weight to reproduce and therefore remain edible year round.⁷¹ The patent examiner rejected the application because "the animal produced by the method claimed is 'controlled by laws of nature and not a manufacture by man that is patentable.'"⁷² The Board of Patent Appeals and Interferences affirmed the patent examiner's rejection, but it disagreed with the conclusion that the oysters were not patentable solely because they were living organisms.⁷³ Instead, the Board based its affirmance on the fact that polyploidy had been produced previously in another oyster species. The *Allen* process, therefore, failed the nonobviousness test of section 103 of the

67. *Id.* at 317-18.

68. *Id.* at 319 (Brennan, J., dissenting).

69. 2 U.S.P.Q.2d (BNA) 1425 (1987).

70. PATENTING LIFE, *supra* note 1, at 8. For data on the number of biotechnology patents pending, see *supra* note 4 and accompanying text.

71. See *Allen*, 2 U.S.P.Q.2d at 1425, 1428.

72. *Id.* at 1426 (quoting the patent examiner).

73. See *id.* at 1426-27.

patent statutes.⁷⁴ The board also reiterated the *Chakrabarty* holding that patent laws should be given wide scope to include human-made life-forms.⁷⁵ Although the applicants in *Allen* did not receive a patent on their oysters, the board clearly endorsed the Supreme Court's view that section 101 allowed patents to be issued for "anything under the sun that is made by man."⁷⁶

3. The Patent and Trademark Office's Announcement⁷⁷

On April 7, 1987, four days after the *Allen* decision, the Patent Office announced that it would accept applications for patents on "nonnaturally occurring nonhuman multicellular living organisms [sic], including animals."⁷⁸ The Patent Office's announcement specified that, in order to be patentable, an animal must be "given a new form, quality, properties or combination not present in the original article existing in nature in accordance with existing law."⁷⁹ Furthermore, an organism which includes human genetic material should be identified as being "non-human" in order to avoid rejection⁸⁰ because human beings are still not patentable subject matter according to a constitutional prohibition on property rights in humans.⁸¹

The Patent Office's decision to allow patents on genetically altered animals has created some controversy.⁸² For example, various animal rights groups and individual farmers filed a lawsuit against the Commissioner of the Patent Office and the Secretary of Commerce⁸³ alleging that the Patent Office's decision violated

74. *See id.*

75. *Id.* at 1426.

76. *Id.* (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980)).

77. Policy Announcement by Donald J. Quigg, Assistant Secretary and Commissioner of Patents and Trademarks (Apr. 7, 1987), *reprinted in* 69 J. PAT. & TRADEMARK OFF. SOC'Y 328 (1987) [hereinafter *Announcement*].

78. *Id.*

79. *Id.*

80. *Announcement*, *supra* note 77.

81. U.S. CONST. amend. XIII, § 1 ("Neither slavery nor involuntary servitude shall exist within the United States"); *Announcement*, *supra* note 77 ("A claim directed to or including within its scope a human being will not be considered to be patentable subject matter [because] exclusive property right in a human being is prohibited by the Constitution.").

82. *See, e.g., Patents*, *supra* note 2, at A-6 (Representative Robert Kastenmeier "emphasized that Congress, not the Patent Office, should determine whether the law allow[s] genetically altered animals to be patented.").

83. *See Animal Legal Defense Fund v. Quigg*, 710 F Supp. 728 (N.D. Cal. 1989), *appeal dismissed*, 900 F.2d 195 (9th Cir. 1990).

appropriate procedures for administrative rulemaking.⁸⁴ A federal district court held that the rule was properly promulgated, but did not consider the larger question of whether the Patent Office exceeded its authority by deciding to issue animal patents.⁸⁵ The court did comment, however, that the Patent Office's "interpretation of *Chakrabarty* as having application beyond unicellular organisms [was] a fair one."⁸⁶

In April 1988, the Patent Office granted the first patent on a multicellular organism.⁸⁷ The patent was issued to Harvard University, where researchers in genetic engineering had developed a mouse which was particularly susceptible to cancer. Harvard gave an executive license to practice the "OncoMouse" patent to E.I. du Pont de Nemours & Co. ("Du Pont") because it was the major research sponsor.⁸⁸ Du Pont plans to license its OncoMouse invention in two ways. First, academic researchers will be required to pay \$50.00 per mouse, but will not be charged for the license.⁸⁹ However, these researchers will be limited to reproducing only 100 OncoMice.⁹⁰ Second, commercial groups that plan to profit from OncoMouse products will pay the \$50.00 per mouse charge and may be required to pay an additional licensing fee in advance.⁹¹ With respect to commercial groups, Du Pont also "reserve[s] the right to charge royalties for offspring of its OncoMouse reproduced in a private lab, and to claim an economic interest in any drug or therapy that results from the use of OncoMouse."⁹²

84. Plaintiffs claimed "that the defendants have promulgated a rule in violation of the Administrative Procedure Act by failing to provide for a period of public notice and comment [and by] promulgat[ing a rule] in excess of defendants' statutory authority." *Id.* at 729 (citations omitted).

85. *Id.* at 732.

86. *Id.* at 731.

87. PATENTING LIFE, *supra* note 1, at 12. The patent describes "[a] transgenic non-human mammal all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said mammal, or an ancestor of said mammal, at an embryonic stage said mammal being a rodent said rodent being a mouse." Transgenic Non-human Mammal, Patent and Trademark Office, U.S. Patent No. 4,736,866 (1988).

88. PATENTING LIFE, *supra* note 1, at 12. Du Pont stated that it received about 10,000 pre-orders for OncoMouse, with an estimated market value in the 1990s ranging from \$1,000,000 to \$25,000,000. Kaplan, *supra* note 2, at 62.

89. Kaplan, *supra* note 2, at 62.

90. *Id.*

91. *Id.*

92. *Id.* Du Pont believes that because use of the mouse could "speed up [] research by as much as a year [and] '[t]ime has value,'" it is justified in claiming an interest

III. CONTROVERSY AND CURRENT PROPOSALS

The Patent Office's decision to allow patenting of multicellular animals has ignited controversy over research in biotechnology and bioengineering in general, and the patenting of animals in particular. This section briefly surveys the moral and ethical issues surrounding the Patent Office's decision, summarizes the particular problems associated with patenting animals, and critiques specific proposals that have been presented to Congress. This information provides a useful background for the development of effective legislation.

A. The Controversy Over Patenting Animals

Although the Patent Office's announcement⁹³ states the agency's position that multicellular animals are patentable, it does not address concerns that animals are not appropriate subject matter for patent law. Those who favor patenting animals claim that restricting patents on animals would curtail research in biotechnology and subsequently jeopardize thousands of jobs as well as the nation's ability to compete globally in the agricultural market.⁹⁴ Those who oppose continued patenting of multicellular organisms argue that encouraging such inventions will inevitably cause numerous ethical and environmental problems.⁹⁵

Opponents of animal patentability focus their arguments on controversial biotechnological research rather than on specific problems with patenting the results of the research.⁹⁶ For example, opponents argue that advances in biotechnology interfere with

in any product or process developed through testing on OncoMouse. *Id.*

93. For a discussion of the announcement, see *supra* text accompanying notes 77-86.

94. Dresser, *supra* note 43, at 409.

95. It is beyond the scope of this note to engage in further examination of these criticisms. For a more detailed discussion of the moral and ethical issues surrounding animal patenting and biotechnology, see PATENTING LIFE, *supra* note 1, at 17-18; Dresser, *supra* note 43, at 407-09; Merges, *supra* note 29, at 1058-62; Note, *Genetic Engineering: Innovation and Risk Minimization*, 57 GEO. WASH. L. REV. 100, 114-19 (1988). For a discussion on environmental concerns arising from the patenting of multicellular organisms, see Dresser, *supra* note 43, at 410-14 (discussing general concerns with "interference with the natural world" and emphasizing doubts regarding capacity for environmental risk assessment); Merges, *supra* note 29, at 1056-58 (discussing fear of immediate ecological disaster, indirect effects of population imbalance, and gene pool depletion); Note, *supra*, at 119-25 (1988).

96. See, e.g., Dresser, *supra* note 43, at 424 ("[M]any of the fears expressed about animal patenting bear on the broader issue of whether scientists should be permitted to manipulate higher animal life at all.").

the natural world by blurring the line between species, thus destroying "species integrity"⁹⁷ Another commonly articulated argument is that patenting multicellular organisms will increase experimentation and subsequent suffering of laboratory animals.⁹⁸ Opponents also claim that advances in biotechnology that involve the addition of human genes to animals may eventually lead to the devaluation of human life.⁹⁹

Proponents of animal patentability argue that limiting patent law is not an appropriate way to discourage or ban research in biotechnology.¹⁰⁰ Unlike the Environmental Protection Agency, the National Institutes of Health, the Food and Drug Administration, and the United States Department of Agriculture, the Patent Office is not a "watchdog agency"¹⁰¹ Rather, its purpose is to administer the patent statutes as developed by Congress.¹⁰²

Patent law, however, has been employed in the past to prohibit the production of innovations deemed "bad" or "immoral." From the nineteenth century until halfway through the twentieth century, for example, courts were willing to withhold patents on "inventions used to defraud buyers" as well as gambling machines.¹⁰³ Congress has since seen fit to statutorily exclude only one type of invention from patent protection — nuclear weapons.¹⁰⁴

Although the patent statutes may not be the appropriate fo-

97. *Id.* at 410-14. The term "species integrity," coined by Jeremy Rifkin, refers to the preservation of the natural genetic code of a species, particularly humans. In a philosophical sense, the genetic code is an inherent aspect of one's being. Thus, proponents of "species integrity" view tampering with the genetic code as altering the nature of humanity. *Id.* at 411.

98. *Id.* at 410, 422-24.

99. *Id.* at 410, 415-17. While researchers have not yet succeeded in developing animal-human hybrids, the creation of hybrids of sheep and goats suggests that the possibility is not remote. *Id.* at 415.

100. See *Hearings*, *supra* note 23, at 576 (letter from Donald W. Peterson and Donald J. Quigg, Assistant Secretary and Commissioner, Patents and Trademarks, to Senator DeConcini) (asserting that moral and ethical issues associated with the patenting of animals are resolved more appropriately by the Department of Agriculture and regulatory agencies since patents focus solely on the merits of the invention and are "neutral with respect to [moral] issues."); Merges, *supra* note 29, at 1067-68 ("The patent system normally is not the proper place to conduct technology assessment [moral problems], if they eventually arise, should be dealt with outside the patent law.").

101. Note, *supra* note 29, at 324 ("[T]he [Patent Office] does not evaluate the safety, morality or probable economic impact of any invention.").

102. See U.S. CONST., art. I, § 8; 35 U.S.C. § 1 (1988).

103. See Merges, *supra* note 29, at 1062.

104. See *supra* note 29 and accompanying text.

rum for addressing the moral and ethical concerns surrounding animal patentability, ignoring these issues will not lead to a resolution. Congress has recognized the gravity of this situation and recommended formation of the Biotechnology Science Coordinating Committee.¹⁰⁵ Such a committee is better able to address any controversial matters.

B. Problems With Patenting Animals Under Current Patent Law

Although the Supreme Court declared that a human-made multicellular organism is patentable in the same manner as any other invention,¹⁰⁶ the fact remains that an animal is nothing like a mousetrap or an electronic appliance or any other kind of routinely patented invention.¹⁰⁷ Contemporary patent law, however, does not clearly indicate how an applicant for an animal patent might satisfy the applicable statutory requirements; nor does it provide for the special uses of animals in agriculture and research. This section examines specific problems faced by inventors applying for patents on multicellular organisms.

1. Depository requirements

One problem encountered by animal patent applicants is satisfying the enabling requirement of section 112.¹⁰⁸ It is unclear

105. See H.R. 1557, 101st Cong., 1st Sess. (1989). The committee would be established as part of the Office of Science and Technology Policy in the Executive Office of the President. *Id.* at § 101. Its functions would be:

- (1) to serve as a coordinating forum for addressing scientific problems, sharing information, and developing consensus with respect to methods for evaluating potential risks to human health and the environment which are or may be caused by genetically-engineered animals,
- (2) to promote uniformity in the development of review procedures and assessments for evaluating such risks,
- (3) to facilitate continuing cooperation among Federal agencies on emerging scientific issues related to such animals and such risks,
- (4) to identify gaps in scientific knowledge with respect to such animals and such risks, and
- (5) to develop guidelines to govern good laboratory and good manufacturing practices in the biotechnology sciences.

Id. at § 102(a)(1)-(5).

106. See *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980).

107. See *Hearings*, *supra* note 23, at 183 (testimony of Professor Robert Merges) (a patented animal is unlike other patented technologies in that no active human intervention is necessary for the animal to be copied).

108. 35 U.S.C. § 112 (1988); see *supra* text accompanying note 34.

whether a written description of an animal will enable one "skilled in the art" to accurately reproduce the invention.¹⁰⁹ Currently, when the Patent Office determines that a written description of an organism is inadequate, the applicant may deposit a sample of the "biological starting material" to supplement the description.¹¹⁰ However, Patent Office Commissioner Donald Quigg has stated that no deposit is needed when "a new breed is reproduced by such common genetic engineering techniques as the injection of readily available DNA into an ovum of a well-known breed."¹¹¹ In other words, no deposit is necessary when widely used transgenic methods and materials are employed to produce the animal.

Because inventors of multicellular organisms often have difficulty satisfying the patent statutes with adequate descriptions of living creations, they face an additional cost that no other inventors face: the cost of making deposits.¹¹² According to the Patent Office, animal patenting is unique in this respect. "No other arts are known where words alone may be incapable of describing an invention sufficiently to enable one skilled in the art to make and use it in a reproducible manner."¹¹³

If classically bred animals are defined as patentable inventions,¹¹⁴ even more deposit questions will arise. Classically bred animals are the offspring of animals that externally exhibit desira-

109. *Id.*

110. See *Hearings, supra* note 23, at 578 (letter from Donald W. Peterson and Donald J. Quigg, Assistant Secretary and Commissioner of Patents and Trademarks, to Senator DeConcini). The applicant decides what material to deposit, but the patent examiner decides whether the deposit is satisfactory. *Id.* If a deposit is required, instead of depositing an entire animal, the "plasmids used in the transgenic method [are] deposited [and] the standard technique by which the deposited plasmid DNA can be introduced into cells [is described] so that the benefits of the invention can be realized." Clark, *Animal Invention Protection*, 16 AM. INTELL. PROP. L.A.Q.J. 442, 455 (1988-89).

111. *Id.* at 579.

112. See Note, *Microorganisms and the Patent Office: To Deposit or Not to Deposit, That is the Question*, 52 FORDHAM L. REV. 592, 602 (1984) (estimating deposit costs to range between \$380 to and \$870 per deposit); see also PATENTING LIFE, *supra* note 1, at 21 (table 1-5) (costs associated with culture deposits range from \$500.00 to \$670.00). Currently, there is no depository willing to accept the deposit of animals. *Id.* at 20.

113. 53 Fed. Reg. 39,420, 39,424 (1988) (to be codified at 37 C.F.R. pt. 1 (proposed Oct. 6, 1988) (Patent Office comments on proposed rule changes to 37 C.F.R. pt. 1)).

114. Currently, the Patent Office has not adopted general guidelines on the patentability of classically bred animals under section 101. Clark, *supra* note 110, at 444. Apparently, this question is decided on a case-by-case basis with the result largely depending on which patent examiner reviews the application. *Id.*

ble characteristics.¹¹⁵ A depository for classically bred animals would therefore have to house "living, breathing, reproducing animals." This situation may present insurmountable problems.¹¹⁶ For instance, the animals would have to be kept apart to prevent the spread of disease which could infect or destroy all of the deposits.¹¹⁷ Furthermore, the depository would have to maintain more than one mating pair for each patent as a precaution against death or infertility.¹¹⁸

The Patent Office recently promulgated the Rules for Deposit of Biological Materials for Patent Purposes ("Rules").¹¹⁹ Under the Rules, biological material includes any "material that is capable of self-replication either directly or indirectly."¹²⁰ Applicants must deposit biological material when it is necessary to fully comply with the requirements of section 112; that is, when a written description of the invention would be inadequate.¹²¹ A deposit of the biological material is not required, however, if the original material is known and readily available to the public or can be made or isolated easily.¹²² The patent examiner determines the ne-

115. See *supra* notes 37-39 and accompanying text.

116. Clark, *supra* note 110, at 449.

117. *Id.*

118. *Id.*

119. 54 Fed. Reg. 34,880 (1989) (to be codified at 37 C.F.R. pt. 1). The Rules deal primarily with transgenically produced organisms and do not address the issues surrounding deposits for classically bred animals.

120. *Id.* (to be codified at 37 C.F.R. § 1.801). There remains the question of whether the deposit of a mating pair of animals would satisfy the self-replication requirement. Although the pair could certainly reproduce itself, it would differ vastly from the representative examples included in the Rules: "Representative examples include bacteria, fungi including yeast, algae, protozoa, eukaryotic cells, cell lines, hybridomas, plasmids, viruses, plant tissue cells, lichens and seeds." *Id.* The comments to this section state that this list is "non-exhaustive" and that self-replication includes "those situations where the biological material is only capable of replication when another self-replicating biological material is present." *Id.* at 34,874 (discussing rule to be codified at 37 C.F.R. § 1.801). However,

these rules are intended to address procedural matters in the deposit of biological material for patent purposes, and are not designed to decide such substantive issues as whether a deposit of a particular organism or material would be recognized or needed to be made for the purposes of satisfying the statutory requirements for patentability under 35 U.S.C. [§ 112

Id.

121. 54 Fed. Reg. at 34,864 (discussing rule to be codified at 37 C.F.R. § 1.802(b)).

122. *Id.* Some factors to be considered in determining whether a biological material is known and readily available to the public include:

commercial availability, references to the biological material in printed publications, declarations of accessibility by those working in the field, evidence of predictable isolation techniques, or an existing deposit made in accordance with these rules. Each factor may or may not be sufficient alone to demonstrate that

cessity and adequacy of each deposit.¹²³ The Rules also allow an applicant to deposit biological material even when the claimed invention can be effectively described in writing, does not rely on biological material, or is not itself biological material.¹²⁴

According to the Rules, a patent applicant who makes a deposit of biological material must do so at an appropriate facility.¹²⁵ An appropriate facility is any International Depository Authority or other depository recognized as suitable by the Patent Office.¹²⁶ Currently, there are no depositories willing to accept animals for deposit due to such factors as prohibitive maintenance costs, possible adverse publicity, uncertain disposition of offspring, and impracticality of keeping samples alive for lengthy time periods.¹²⁷ An applicant must make any necessary deposit of biological material either before filing the patent application or while the application is pending.¹²⁸ If a deposit becomes contaminated or loses its ability to function as claimed, it must be replaced with a supplemental deposit upon immediate notification to the depositor.¹²⁹ The depository will maintain a deposit "for a term of at least thirty years and at least five years after the most recent request for the furnishing of a sample of the deposit was received by the depository"¹³⁰ Finally, the deposit must be capable of self-replication, either directly or indirectly, at the time of

the biological material is known and readily available.

Id. at 34,875, (discussion of rule to be codified at 37 C.F.R. § 1.802).

123. *Id.* at 34,882 (to be codified at 37 C.F.R. § 1.809).

124. *Id.* at 34,868 (discussion of rule to be codified at 37 C.F.R. § 1.802(a)).

125. The comments to the rules list nineteen depositories which are recognized as International Depository Authorities ("IDA"), three of which are in the United States: the Agricultural Research Culture Collection, the American Type Culture Collection, and In Vitro International, Inc. *Id.* at 34,876 (discussing rule to be codified at 37 C.F.R. § 1.803). Criteria for determining the adequacy of a non-IDA depository include whether the depository has had a continuous existence, is independent of the depositor's control, possesses sufficient staff and facilities to preserve the deposit properly, follows sufficient safety measures to guard against loss of biological material, exhibits impartiality and objectivity, furnishes samples of deposited matter in a proper and timely manner, and promptly notifies depositors if unable to furnish samples. *Id.* at 34,881 (to be codified at 37 C.F.R. § 1.803).

126. *Id.* at 34,881 (to be codified at 37 C.F.R. § 1.803).

127. See PATENTING LIFE, *supra* note 1, at 20.

128. 54 Fed. Reg. 34,880, 34,881 (1989) (to be codified at 37 C.F.R. § 1.804).

129. *Id.* at 34,881-82 (to be codified at 37 C.F.R. § 1.805).

130. *Id.* at 34,882 (to be codified at 37 C.F.R. § 1.806). This rule highlights the difficulty of patenting classically bred animals. Maintaining a deposit of an animal for at least 30 years would be extremely difficult because most animals do not live that long and animals that do survive for 30 years would be expensive to maintain over that period.

the deposit.¹³¹

The written description of each patented invention is available to the public.¹³² Likewise, the public must have access to a deposit made as part of a patent application.¹³³ However, the depositor may require that a depository refuse to furnish a sample unless the third party's request is in writing, is dated, and contains the name and address of the requesting party.¹³⁴ The depository must also communicate this information, in writing, to the depositor.¹³⁵

2. Family farm exemption

Other concerns about patenting animals revolve around economic fears, particularly the economic survival of family farms. Some farmers are concerned that, in order to breed and sell their animals, they will have to pay large licensing fees and royalties to biotechnology companies holding the patents.¹³⁶ This is a valid concern under current patent laws, as intentional breeding of patented animals probably amounts to patent infringement.¹³⁷

The opposing argument is that patenting farm animals will pose no significant economic problems for farmers. The cost of any patented good, including an animal, is constrained by the cost of available substitutes.¹³⁸ Thus, if the cost of a patented animal or the right to breed it exceeds the benefit to the farmer in terms of increased production and profit, the farmer will buy an unpatented animal.¹³⁹

A farmer's exemption for patented animals would allow farmers to use patented animals and their offspring for normal

131. See *id.* at 34,882 (to be codified at 37 C.F.R. § 1.807).

132. See 35 U.S.C. § 112 (1988).

133. See 54 Fed. Reg. 34,880, 34,882 (1989) (to be codified at 37 C.F.R. § 1.808).

134. *Id.*

135. *Id.*

136. See *Hearings, supra* note 23, at 337-38 (statement of Debra Schwarze, Wisconsin Family Defense Fund).

137. *Merges, supra* note 29, at 1068. Patent Commissioner Donald Quigg confirmed this assumption in a letter to Senator Dennis DeConcini: "Unauthorized acts of reproduction (*i.e.*, the breeding of patented animals to increase their numbers) would, therefore, seem to be an infringement. This view is consistent with the doctrine of patent law that a purchaser of a patented invention may repair, but not reconstruct, it." *Hearings, supra* note 23, at 579.

138. See *Hearings, supra* note 23, at 168 (testimony of Reid G. Adler, attorney with Finnegan, Henderson, Farabow, Garrett & Dunner).

139. *Id.*

breeding purposes on their farms.¹⁴⁰ However, an exemption may remove economic incentives for developing genetically engineered animals. The research leading to development of these animals is expensive; thus, developers depend on royalty revenues from their inventions.¹⁴¹

3. Research exemption

Like farmers, researchers have a special interest in protecting themselves from patent infringement suits involving patented multicellular organisms. Under a research exemption to the patent law, a researcher is allowed to experiment with a patented animal without fear of an infringement suit so long as he or she is involved in "bona fide research activities designed to further scientific knowledge."¹⁴² Current case law, but not statutory law, holds that

where [the patented invention] is made or used as an experiment, whether for the gratification of scientific tastes, or for curiosity, or for amusement, the interests of the patentee are not antagonized, the sole effect being of an intellectual character in the promotion of the employer's knowledge or the relaxation afforded to his mind.¹⁴³

This experimental use exception is interpreted narrowly by courts.¹⁴⁴

140. See *Merges*, *supra* note 29, at 1070-73. The exemption would be similar to the farmer's crop exemption provided by the Plant Variety Protection Act:

[This title] shall not infringe any right hereunder for a person to save seed produced by him from seed obtained [from] the owner of the [patented] variety [and] it shall not infringe any right hereunder for a person, whose primary farming occupation is the growing of crops for sale for other than reproductive purposes, to sell such saved seed to other persons so engaged

7 U.S.C. § 2543 (1988).

141. See *Schneider*, *Patent Proposal Adopted By Panel*, N.Y. Times, Aug. 3, 1988, at 6, col. 8.

142. *Merges*, *supra* note 29, at 1073.

143. *Roche Prods. v. Bolar Pharmaceutical Co.*, 733 F.2d 858, 862 (Fed. Cir. 1984) (emphasis omitted) (quoting W. ROBINSON, *THE LAW OF PATENTS FOR USEFUL INVENTIONS* § 898 (1890)). Although there is no research exemption in the general patent statutes, Congress did include one in the Plant Variety Protection Act, providing that the "use and reproduction of a protected variety for bona fide research shall not constitute an infringement." 7 U.S.C. § 2544 (1988).

144. See, e.g., *Roche Prods.*, 733 F.2d at 863 (holding that the experimental use exception is not available when the patented invention is used to further the infringer's business interests); *American Standard, Inc. v. Pfizer, Inc.*, 722 F. Supp. 86, 102-03 (D. Del. 1989) (holding that experimental use exception is limited to medical devices used to obtain information for the Food and Drug Administration).

The Patent Office and the Supreme Court agree that living organisms are patentable. However, many details must be worked out by Congress so these inventions receive proper patent protection. The need for a depository requirement, a family farm exemption, and a research exemption are issues that Congress must address in order to clarify the process of patenting multicellular organisms.

C. Critique of proposed legislation

Although Congress has not passed legislation amending the patent laws to provide for multicellular organisms, it has considered several bills on this subject. In fact, animal patenting legislation has been proposed during each of the past three sessions of Congress.¹⁴⁵ While Congress recognizes the need for reform, it has failed to produce an adequate bill. Nevertheless, an examination of the proposed bills exposes potential benefits and detriments that should be considered in any future proposals.

1. H.R. 3119,¹⁴⁶ S. 2111,¹⁴⁷ and H.R. 3247¹⁴⁸

H.R. 3119, S. 2111 and H.R. 3247 propose prohibiting the issuance of patents for genetically engineered animals.¹⁴⁹ H.R. 3119 places a two year moratorium on such patents because "the patenting of genetically engineered invertebrate and vertebrate animals raises profound economic, environmental, and ethical

145. See *infra* notes 146-86.

146. H.R. 3119, 100th Cong., 1st Sess. (1987).

147. S. 2111, 100th Cong., 2d Sess. (1988).

148. H.R. 3247, 101st Cong., 1st Sess. (1989).

149. H.R. 3119 provides that for a two year period:

[V]ertebrate or invertebrate animals, modified, altered, or in any way changed through genetic engineering technology shall not be considered matter within the confines of patentability and shall not be patentable within the meaning of section 101 or section 102 Any patent previously granted for any such animals is hereby revoked.

H.R. 3119, *supra* note 146, § 2 (amending 35 U.S.C. § 105 (1988)).

S. 2111 would amend the patent law so that "[v]ertebrate or invertebrate animals, modified, altered, or in any way changed through engineering technology, including genetic engineering, shall not be considered matter within the confines of patentability and shall not be patentable [A]ny patent previously granted for any such animals is hereby revoked." S. 2111, *supra* note 147, § 1 (amending 35 U.S.C. § 105).

H.R. 3247 provides that "[d]uring the 2-year period any vertebrate or invertebrate animal that is modified, altered, or in any way changed through genetic engineering technology shall not be considered to be patentable subject matter " H.R. 3247, *supra* note 148, § 1 (amending 35 U.S.C. § 105).

questions which Congress has not had the opportunity to fully address."¹⁵⁰ According to Representative Cardin, sponsor of H.R. 3247, a moratorium "provide[s] [Congress] with the necessary time to determine whether or not we need to make improvements in our patent law to deal directly with the patenting of animals."¹⁵¹ S. 2111 goes even further by banning the patenting of animals completely.¹⁵² Under H.R. 3119 and S. 2111, any micro-organism patent previously granted is revoked,¹⁵³ whereas H.R. 3247 leaves existing patents intact and forbids only future patents.¹⁵⁴ Furthermore, H.R. 3247 is not applicable to any animal that is subject to regulatory review and approval under federal environmental, health, safety, and bioethical standards before it is commercialized.¹⁵⁵

Despite the intention of these bills, it is unlikely that a moratorium would effectively halt research in biotechnology. The Supreme Court has also predicted this result: "The large amount of research that has already occurred when no researcher had sure knowledge that patent protection would be available suggests that legislative fiat as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides."¹⁵⁶ Instead, a moratorium would yield undesirable results. First, adoption of any of these three bills would mark the first time in history that patent legislation has overturned an existing Patent Office policy.¹⁵⁷ According to the Patent Office, "[a] moratorium would create the unfortunate precedent of deferring patent rights on grounds totally unrelated to the merits of the invention, thus counteracting our efforts to strengthen intellectual property rights for American industry."¹⁵⁸ The undesirable precedent may encourage future limitations on patents issued for other types of inventions, a purpose for which the patent

150. H.R. 3119, *supra* note 146, § 1, at 1.

151. 135 Cong. Rec. H3008 (daily ed. Sept. 12, 1989).

152. S. 2111, *supra* note 147, § 1.

153. H.R. 3119, *supra* note 146, § 1; S. 2111, *supra* note 147, § 1.

154. See H.R. 3247, *supra* note 143.

155. *Id.* § 1.

156. *Diamond v. Chakrabarty*, 447 U.S. 303, 317 (1980).

157. Note, *Hindering the Progress of Science: The Use of the Patent System to Regulate Research on Genetically Altered Animals*, 16 FORDHAM URB. L.J. 441, 444 n.6 (1987-88).

158. *Hearings*, *supra* note 23, at 576 (letter from Donald Quigg, Assistant Secretary and Commissioner of Patents and Trademarks, to Senator DeConcini).

system is not designed.¹⁵⁹ Second, the revocation of a previously granted patent may constitute a taking which requires the federal government to compensate the patent owner.¹⁶⁰ Although a moratorium might give Congress some "breathing room" to contemplate the answers to "profound economic, environmental and ethical questions,"¹⁶¹ it may also result in unacceptable consequences.

A moratorium on patenting animals would cause one further problem: without patent protection, developers of multicellular organisms may decide to pursue trade secret protection for their inventions.¹⁶² Under trade secrecy, an inventor conceals important information about an invention from competitors in order to prevent duplication of the invention.¹⁶³ If the information is disclosed, the protection is lost forever.¹⁶⁴ Thus, "a trade secret owner has a strong incentive to prevent disclosure of his discovery and to invest time and money controlling access to his invention."¹⁶⁵ Should inventors resort to trade secrecy protection, fewer new products might enter the market, "thereby preventing public access to life-saving inventions."¹⁶⁶ Furthermore, trade secret protection can be complex and expensive to establish and maintain,¹⁶⁷ causing hard-

159. See Note, *supra* note 29, at 324 (arguing that the Patent Office and patent system do not serve a "watchdog" function).

160. See H.R. 3119, *supra* note 146, § 1 ("untimely action on this issue could unnecessarily expose patent holders to the revocation of their patents and expose the Government to financial liability for their restitution"). While it is beyond the scope of this note to fully explore the constitutional "takings clause" issue as it relates to patenting multicellular organisms, it is important to note that trying to resolve these issues by overruling retrospectively the announced policy of the Patent Office could create even more problems than it solves. Congress seemed to be aware of this "takings clause" issue when it included a "right to compensation" section in its amendment to the patent law disallowing patents on inventions "in which the Government has a property interest" because of national security. 35 U.S.C. §§ 181, 183 (1988).

161. H.R. 3119, *supra* note 146, § 1.

162. Note, *Life, the Patent Office and Everything: Patentability of Lifeforms Created Through Bioengineering Techniques*, 9 U. BRIDGEPORT L. REV. 413, 441 (1988).

163. See PATENTING LIFE, *supra* note 1, at 118. "Companies opting for secrecy rely on trade secrets and seek to conceal crucial details or key processes from competitors." *Id.* (emphasis deleted).

164. See *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 490 (1973) ("The holder of a trade secret takes a substantial risk that the secret will be passed on to his competitors, by theft or by breach of a confidential relationship."); PATENTING LIFE, *supra* note 1, at 46 ("Once the information becomes publicly known it loses its status as a trade secret."); Note, *supra* note 95, at 108 ("A trade secret is valuable only as long as it is kept secret.").

165. See Note, *supra* note 95, at 108.

166. *Id.* at 109.

167. Note, *supra* note 157, at 444.

ship for new companies trying to enter the market.¹⁶⁸

2. H.R. 4970¹⁶⁹

Unlike the bills previously discussed,¹⁷⁰ H.R. 4970 does not impose a moratorium on patenting multicellular organisms. Instead, H.R. 4970 implies that such organisms are patentable subject matter, even though the bill never expressly designates them as patentable. H.R. 4970 provides a farmer's exemption,¹⁷¹ a research exemption,¹⁷² and a voluntary deposit provision to satisfy patent enabling requirements.¹⁷³ The farmer's exemption protects the small farmer from patent infringement liability based on breeding, using, or selling transgenic farm animals, unless the activity is done for "reproductive purposes, including use at stud or the provision of embryos."¹⁷⁴ The research exemption embodies the contention that using an invention to further scientific inquiry is not patent infringement.¹⁷⁵ The deposit requirement gives a great deal of discretion to the Patent Office, allowing the Commissioner to establish the conditions under which a deposit will be accepted to satisfy the enabling requirement of section 112.¹⁷⁶ However, the bill provides some limit to this discretion by codify-

168. See *Hearings, supra* note 23, at 454 (statement of Geoffrey M. Karry, attorney with Dickstein, Shapiro & Morin) ("[P]atents are of particular importance to small start-up companies that are attempting to raise capital. [P]rohibiting patents on transgenic animals could make it extremely difficult for these companies to raise needed capital"); *Id.* at 27 (statement of Rene D. Tegtmeyer, Assistant Commissioner of Patents) ("[P]atents are of special value to the smaller company, the new entrant, who needs financing, needs support, and really needs to depend upon the exclusivity granted by a patent in order to hold onto a market position and break into a new market.").

169. H.R. 4970, 100th Cong., 2d Sess. (1988).

170. See *supra* notes 146-68 and accompanying text.

171. H.R. 4970, *supra* note 169, § 2 (proposed amendment to 35 U.S.C. § 271 (1988)) ("It shall not be an act of infringement for a person whose occupation is farming to reproduce through breeding, use, or sell a patented transgenic farm animal"). This bill would limit the exemption to those farmers earning less than \$500,000 per year in gross receipts from the farm and those who "conduct farming activities as a single-family enterprise." *Id.*

172. *Id.* § 2 (proposed amendment to 35 U.S.C. § 112 (1988)) ("[I]t shall not be an act of infringement to make or use a patented invention consisting of a genetically altered animal solely for research or experimentation without any commercial intent or purpose.").

173. *Id.* § 3 (proposed amendment to 35 U.S.C. § 112 (1988)) ("[T]he Commissioner may accept a deposit of biological material to satisfy any requirement of this section if made accessible under such conditions as the Commissioner may require.").

174. *Id.* § 2 (proposed amendment to 35 U.S.C. § 271 (1988)).

175. See *supra* text accompanying notes 142-44.

176. See H.R. 4970, *supra* note 169, § 3 (proposed amendment to 35 U.S.C. § 112 (1988)).

ing the Patent Office's ruling "that human beings are not patentable subject matter."¹⁷⁷

Although this bill avoids the pitfalls created by the moratoriums of H.R. 3119, H.R. 3247, and S. 2111,¹⁷⁸ it does not clearly identify those animals that are patentable. For example, the bill does not expressly exclude classically bred animals from patentability. It also fails to include them within the farmers' exemption which refers to and defines only transgenic farm animals.¹⁷⁹ Therefore, a farmer may be held liable for patent infringement for breeding, using, or selling classically bred farm animals.¹⁸⁰ The research exemption is also ambiguous. The exemption specifically refers to "a patented invention consisting of a genetically altered animal,"¹⁸¹ but fails to define such an animal. For instance, there is no indication whether a classically bred mouse that is prone to cancer qualifies as a genetically altered animal covered by the research exemption.

3. H.R. 1556¹⁸²

In many ways, H.R. 1556 parallels H.R. 4970. H.R. 1556 provides a farmer's exemption, although the farm is not subject to any size requirement.¹⁸³ While H.R. 1556 does not provide a research exemption, the depository requirement¹⁸⁴ and the ban on

177. *Id.* § 4 (proposed amendment to 35 U.S.C. § 101 (1988)).

178. *See supra* text accompanying notes 156-68.

179. H.R. 4970, *supra* note 169, § 2 ("a 'transgenic farm animal' is a farm animal whose germ cells contain genetic material originally derived from another animal other than the parent of the farm animal"). For further discussion of transgenic animals, see *supra* note 40 and accompanying text.

180. One witness before the House Courts, Civil Liberties, and Administration of Justice Subcommittee emphasized the need for patent legislation to provide explicitly for classically bred animals in order to be effective:

The bacteria which was at issue in the *Chakrabarty* decision was not genetically engineered. The oyster which was at issue before the Patent Office was also not genetically engineered. The allowance of patent protection for animals will apply to conventionally bred as well as genetically engineered animals. And Charlie Van Horn the director of the Biotech Group at the Patent Office stated that the animals must be created through the hand of man, but that hand does not necessarily have to hold a test tube.

Hearings, supra note 23, at 353 (statement of Nicholas Seay, patent attorney).

181. H.R. 4970, *supra* note 169, § 2 (proposed amendment to 35 U.S.C. § 271 (1988)).

182. H.R. 1556, 101st Cong., 1st Sess. (1989).

183. *See id.* § 2 (proposed amendment to 35 U.S.C. § 271 (1988)).

184. *Id.* § 3 (proposing an amendment to 35 U.S.C. § 112 (1988)).

patenting human beings¹⁸⁵ are identical to those in H.R. 4970.¹⁸⁶

If enacted, H.R. 1556 would cause considerable difficulties for farmers and researchers alike. Like H.R. 4970, H.R. 1556 does not expressly include or exclude classically bred animals from the patent laws. Under this bill, therefore, farmers with farms of all sizes are subject to patent infringement liability if some classically bred animals are ultimately found to be patentable. Furthermore, researchers using either transgenic or classically bred animals in their experiments must consider their potential liability in the absence of a research exemption.

4. The Virginia Proposal¹⁸⁷

A note published in the *Virginia Law Review* offers a proposal for legislation dealing with the patentability of multicellular organisms (the "Virginia Proposal"). The Virginia Proposal allows the patenting of "any distinct variety of multicellular animal, other than one found in nature, whose distinct characteristic(s) can be reproduced and are stable in the animal's offspring

"¹⁸⁸ If the variety of animal is "novel," then it satisfies the nonobviousness requirement of section 103 of the patent laws by definition.¹⁸⁹ The Virginia Proposal provides only narrow protection of a new multicellular organism, thus encouraging the original developer to pursue "all the possible fruits of his research

"¹⁹⁰ If the original developer's claim is not exhaustive, then "others have the opportunity to develop new inventions based on the previous work."¹⁹¹ The Virginia Proposal further requires a patent applicant to deposit samples of genetic material in order to satisfy the section 112 enabling requirement.¹⁹² The Virginia Proposal also places the initial burden of proving patent infringement on the patent owner.¹⁹³ If the patent owner successfully proves in-

185. *Id.* § 4 (proposing an amendment to 35 U.S.C. § 101 (1988)).

186. *See supra* text accompanying notes 176-77.

187. Note, *supra* note 20, at 1355-61.

188. *Id.* at 1355 (§ 1 of the Virginia Proposal).

189. *Id.* (§ 2 of the Virginia Proposal).

190. *Id.* at 1358-59 (discussing § 3 of the Virginia Proposal) (It is recognized that "minor modifications in the genetic structure of an organism can significantly alter the properties of the organism.").

191. *Id.* at 1359.

192. *Id.* at 1356 (§ 4 of the Virginia Proposal). No application for a multicellular animal patent will be denied for lack of completeness under 35 U.S.C. § 112 if it is "as complete as is reasonably possible." *Id.*

193. *Id.* (§ 5 of the Virginia Proposal).

fringement, the alleged infringer bears the burden of proving that the patent does not cover his or her animal.¹⁹⁴ Finally, the Patent Commissioner may choose to declare a patented animal open to use if it is deemed "necessary for the health, safety, or welfare of the general public in this country,"¹⁹⁵ so long as the owner of the patent is reimbursed "in an amount not less than a reasonable royalty"¹⁹⁶

While the Virginia Proposal is clearer than the other proposed legislation, it nevertheless fails in some important respects. The Virginia Proposal does not address the issues of transgenic animals used on family farms and in research. Nor does it adequately limit the types of animals which are patentable. By the Virginia Proposal's definition, classically bred, multicellular animals not found in nature are patentable because their characteristics are reproducible and stable in their offspring. However, classically bred animals would be almost impossible to adequately describe for the purposes of the section 112 enabling requirement¹⁹⁷ because their exterior characteristics do not always breed through to offspring.¹⁹⁸ Although section 4 of the Virginia Proposal specifies that such descriptions satisfy the enabling requirement,¹⁹⁹ they may defeat the purpose of section 3 to give other inventors the opportunity to develop new innovations by improving patented inventions or incorporating them into other technologies.²⁰⁰ Furthermore, vague descriptions of classically bred animals would hardly enable one skilled in the art to recreate inventions.²⁰¹

IV A PROPOSAL TO CHANGE THE PATENT LAW

The proposals discussed in Section III of this note do not adequately address the unique problems created by the patenting of multicellular organisms. Congress should therefore try once again to craft legislation clarifying this area of patent law Section IV of

194. *Id.*

195. *Id.* (§ 6 of the Virginia Proposal).

196. *Id.*

197. 35 U.S.C. § 112 (1988).

198. See Note, *supra* note 29, at 316 ("[l]iving inventions pose a special problem because they cannot be adequately described through illustrative diagrams and written text."); *supra* text accompanying notes 37-39.

199. See Note, *supra* note 20, at 1356 (§ 4 of the Virginia Proposal).

200. *Id.* at 1359 (discussing § 3 of the Virginia Proposal).

201. See 35 U.S.C. § 112 (1988).

this note first discusses what should and should not be included and then offers a foundation upon which Congress can build effective legislation. Any amendments to the patent law must include a clear definition of patentable subject matter, a specific deposit provision, a farmer's exemption, and a research exemption.

A. Definition of Patentability

Congress should model the definition of patentable, multicellular organisms after the definition provided in the Plant Variety Protection Act.²⁰² That Act defines patentable plants as "novel varieties" which are distinct, uniform, and stable."²⁰³ In order to be distinct, the novel variety must differ from other known varieties "by one or more identifiable morphological, physiological or other characteristics."²⁰⁴ Uniformity requires that "any variations [of the invention] are describable, predictable and commercially acceptable."²⁰⁵ Finally, a novel variety is stable if it can be "sexually reproduced or reconstituted" and its distinctive characteristics will, in general, not change.²⁰⁶ A similar definition of multicellular organisms would expressly provide that human-altered animals of natural origin are patentable subject matter and require that they satisfy the section 102 novelty requirement.²⁰⁷

Classic breeding techniques will continue to be the predominant method of developing new multicellular organisms, particularly in the animal husbandry discipline.²⁰⁸ Thus, Congress should state unambiguously whether these animals are patentable. The legislation proposed by this note identifies classically bred animals as unpatentable subject matter.²⁰⁹ The problem with patenting classically bred animals is fundamentally one of enablement. While breeders may be able to produce animals with the desired characteristics, even the best breeders have trouble consistently doing so when they rely solely on exterior traits.²¹⁰ Classically bred animals, therefore, do not satisfy the uniformity and stability

202. 7 U.S.C. §§ 2321-2582 (1988).

203. *Id.* § 2401(a).

204. *Id.* § 2401(a)(1).

205. *Id.* § 2401(a)(2).

206. *Id.* § 2401(a)(3).

207. 35 U.S.C. § 102 (1988).

208. See Clark, *supra* note 110, at 443.

209. See *infra* text accompanying note 236.

210. For a discussion of the problems of classical breeding, see *supra* text accompanying note 39.

requirements of the proposed definition.²¹¹ Furthermore, unlike transgenically created animals,²¹² classically bred animals cannot be described in a manner sufficient to allow "one skilled in the art"²¹³ to recreate the inventions reliably. Even requiring deposits of the organisms in lieu of written descriptions does not solve this problem. Mandatory deposits would create almost insurmountable problems for depositories in terms of caring, housing, and maintaining the deposits.²¹⁴ Therefore, classically bred animals are not proper candidates for protection under the United States patent system and should be excluded from it.

B. Deposit Proposal

The Rules for Deposit of Biological Materials for Patent Purposes,²¹⁵ which were recently adopted by the Patent Office, are generally well-crafted and should be retained in any future animal patent legislation enacted by Congress. However, one addition should be made.

The current deposit rules give no clear guidance as to whether a deposit is required for a particular application.²¹⁶ Furthermore, section 112 of the patent laws²¹⁷ does not illuminate the necessity of a deposit. However, "[i]t would be extremely difficult to obtain a written description of multi-cellular organisms or whole animals" that would independently satisfy the enabling requirement of the patent laws.²¹⁸

The better approach, and the one that Congress should adopt, is to require every inventor to deposit a sample of biological material when applying for a patent of an animate invention. Although a rule requiring deposits would make animal patents unique,²¹⁹

211. See *infra* text accompanying notes 234-35.

212. For a discussion of transgenic animals, see *supra* text accompanying notes 40-49.

213. 35 U.S.C. § 112 (1988).

214. For a discussion of the problems faced by depositories maintaining classically bred animals, see *supra* text accompanying notes 114-18.

215. 54 Fed. Reg. 34,864 (1989) (to be codified at 37 C.F.R. pt. 1). For a complete discussion of these rules, see *supra* text accompanying notes 119-35.

216. 54 Fed. Reg. 34,864, 34,874 (1989) (§ 1.801 of the rules is "not designed to decide such substantive issues such as whether a deposit of a particular organism would [need] to be made").

217. 35 U.S.C. § 112 (1988).

218. Pautler, *Patenting of Life Forms: Where Do We Go From Here?*, TRIAL, April 1982, at 47, 49.

219. See 53 Fed. Reg. 39,420, 39,424 (1988) (to be codified at 37 C.F.R. pt. 1)

this is an appropriate reflection of the radical differences between animals and other, more typical, patented inventions. Even under current law, transgenically created animals usually require some sort of deposit.²²⁰ It is, therefore, more efficient to structure the animal patenting process to accommodate these cases routinely. Furthermore, the proposed deposit rule would probably encourage the development of more depositories, which will be needed as more researchers seek to patent their novel varieties of multicellular organisms.

C. Farmer's Exemption

Congress should include a farmer's exemption similar to that proposed in H.R. 4970²²¹ in any future animal patent legislation. A well-crafted farmer's exemption has several benefits. First, it clearly identifies which activities constitute patent infringement by farmers.²²² Second, it reduces the record keeping burden of farmers who would otherwise have to track the use of patented animals and payment of respective royalties.²²³ Finally, a farmer's exemption prevents patent owners from threatening patent infringement actions in order to coerce favorable licensing agreements.²²⁴

A farmer's exemption provision should clearly define the scope of its coverage and simultaneously limit exempted parties to the smallest number consistent with achieving the desired ends. The farmer's exemption should therefore allow a farmer to purchase a patented animal and use it, sell it, or even breed it so long as the resulting animals are not sold to be bred.²²⁵ The exemption proposed by this note reflects a compromise position, balancing the traditional practice of a farmer buying an animal that may be used to produce marketable offspring against the desire to protect the inventor's right to profit from his or her investment

(proposed Oct. 6, 1988) (discussing proposed Rules for Deposit of Biological Materials for Patent Purposes, the Patent Office stated that "[n]o other arts are known where words alone may be incapable of describing an invention").

220. See, e.g., Transgenic Non-human Mammal, Patent and Trademark Office, U.S. Patent No. 4,736,866 (1988) ("Plasmids bearing the fusion genes have been deposited in the American Type Culture Collection").

221. H.R. 4970, *supra* note 169. For a complete discussion of H.R. 4970, see *supra* text accompanying notes 170-81.

222. See Merges, *supra* note 29, at 1072.

223. *Id.*

224. *Id.*

225. See H.R. 4970, *supra* note 169, § 2.

and to encourage further innovations. In other words, the farmer retains the traditional right to breed and use the animal, while the inventor remains protected. Furthermore, when a patented animal is mated with a non-patented animal, a maximum of only sixty percent of the offspring will possess the patented trait.²²⁶ Thus, even with an exemption, a farmer will eventually need to purchase more patented animals to continue receiving the benefit of the desired trait.²²⁷

D Research Exemption

It is especially important that researchers understand what constitutes noninfringing use of patented animals since a "large amount of research that is [performed on animals] by public agencies is in the agricultural sector."²²⁸ Thus, Congress should include a research exemption similar to that contained in H.R. 4970²²⁹ in its changes to the patent law. This exemption would encourage the use of patented animals to promote scientific research and discoveries.²³⁰

E. The Proposed Multicellular Organism Patent Act

Any legislation affecting the patentability of animals must first define which animals are patentable. The legislation must also specify when an inventor needs to make a deposit and include farmer's and researcher's exemptions. In addition, Congress should establish the Biotechnology Science Coordinating Committee proposed in H.R. 1557.²³¹ This committee would be more effective than the patent laws in resolving the very real ethical and policy questions that still plague the biotechnology industry.²³²

226. *Merges*, *supra* note 29, at 1071.

227. *Id.*

228. *Id.* at 1073.

229. *See* H.R. 4970, *supra* note 169, at 1-2; *supra* text accompanying note 175.

230. *See* *Merges*, *supra* note 29, at 1073.

231. *See* H.R. 1557, *supra* note 105, § 1. This committee would be under the control and supervision of the Director of the Office of Science and Technology Policy. Any action taken by the Committee in performing its functions would be considered "an action taken by [the Office of Science and Technology Policy] in the performance of its duties under title IV of the National Science and Technology Policy, Organization, and Priorities Act of 1976." *Id.*

232. For a discussion of the appropriateness of ethical and moral issues in the patenting process, see *supra* text accompanying notes 93-105.

Multicellular Organism Patent Act

§ 1 DEFINITION OF PATENTABLE ANIMALS

Any novel variety of multicellular organism may be patented, except as provided in subsections (b) and (c):

(a) A "novel variety" is one that is: (1) clearly different from other known varieties in one or more identifiable morphological or physiological characteristic(s);²³³

(2) uniform in that it is describable and predictable;²³⁴ and

(3) stable in that it can be sexually reproduced or reconstituted and the distinctive characteristic will be passed on unchanged to at least some of its offspring.²³⁵

(b) Animals created through classic breeding methods are not patentable subject matter.²³⁶

(c) Human beings are not patentable subject matter.²³⁷

§ 2 DEPOSIT REQUIREMENT

A sample of the multicellular organism's biological material must be deposited in a depository approved by the Patent and Trademark Office.²³⁸

(a) It will be the province of the patent examiner to determine if the deposit is acceptable for patent purposes.

(b) The deposit must be maintained for a minimum of thirty years and at least five years after the most recent request received by the depository for a sample of the deposit.²³⁹

(c) If the deposit is damaged or lost during its term in the

233. This definition is derived from the Plant Variety Protection Act. 7 U.S.C. § 2401(a)(1) (1988). For a discussion of the Plant Variety Protection Act as model legislation, see *supra* text accompanying notes 202-07.

234. See 7 U.S.C. § 2401(a)(2) (1988).

235. See *id.* § 2401(a)(3).

236. For a discussion of excluding classically bred animals from patent protection, see *supra* text accompanying notes 208-14.

237. This exception is derived from H.R. 4970, *supra* note 161, § 4; see *supra* text accompanying note 177.

238. The proposed deposit requirements are nearly identical to the Patent Office's Rules for Deposit of Biological Materials for Patent Purposes. See 54 Fed. Reg. 34,864 (1989) (to be codified at 37 C.F.R. pt. 1); *supra* text accompanying notes 119-35. However, the Patent Office rules do not require a deposit "unless access to such material is necessary for the satisfaction of 35 U.S.C. 112." 54 Fed. Reg. 34,880, 34,880 (1989) (to be codified at 37 C.F.R. § 1.802). For a discussion of the reasons favoring a deposit requirement in all cases, see *supra* text accompanying notes 219-20.

239. See 54 Fed. Reg. 34,880, 34,882 (1989) (to be codified at 37 C.F.R. § 1.806).

depository, a supplemental deposit must be made.²⁴⁰

(d) The deposit must, at all times during the term of the deposit, be capable of either direct or indirect self-replication.²⁴¹

§ 3 FARMER'S EXEMPTION

A person whose occupation is farming and whose farm is a single family enterprise may use, sell, or reproduce a patented farm animal through breeding without infringing the patent, subject to the conditions in subsection (c).²⁴²

(a) A "farm" is a single family enterprise if all the management and a substantial portion of the labor are provided by the members of one family.²⁴³

(b) A "farm animal" is any animal used or intended for use as food or fiber.²⁴⁴

(c) The breeding or sale of the animal must not be for reproductive purposes such as providing stud services or embryos.²⁴⁵

§ 4 RESEARCH EXEMPTION

The use of a patented animal solely for research or experimentation, without any commercial intent or purpose, will not be an infringement of the patent.²⁴⁶

V CONCLUSION

While inventors may never be able to perfect the mousetrap, they may be able to perfect the mouse. Clearly, the patent statutes are currently inadequate to solve the problems raised by such inventions. Although several proposals have been made to address

240. See *id.* at 34,881 (to be codified at 37 C.F.R. § 1.805).

241. See *id.* at 34,882 (to be codified at 37 C.F.R. § 1.807). Requiring a deposit that can reproduce the patented organism ensures that the enabling requirement of section 112 is satisfied and eliminates the problem of deciding when the breeding and genetic material are common enough to obviate the deposit requirement. See *supra* text accompanying note 120. Thus, under this proposed legislation, the most likely deposit would be a frozen embryo. However, as cloning techniques are improved, deposits of cells from the multicellular organism would also satisfy the requirement.

242. The farmer's exemption is derived from H.R. 4970, *supra* note 169, § 2; see text accompanying note 174.

243. See H.R. 4970, *supra* note 169, § 2.

244. *Id.*

245. *Id.*

246. The research exemption is derived from H.R. 4970, *supra* note 169, § 2; see *supra* text accompanying note 175.

these problems, they are inadequate for the task.

Congress has the ability to solve the problems surrounding the patentability of multicellular organisms. Well-crafted legislation would clarify the law regarding the patenting of animals. New legislation must clearly define those animals which are patentable and expressly exclude classically bred animals from patentability. The Patent Office's depository rules should be amended to require deposits for all multicellular organism patent applications. Finally, the legislation should include a limited farmer's exemption and a research exemption in order to encourage work in these areas and clarify the boundaries of patent rights. By incorporating these proposals, Congress can indeed build the better mousetrap of improved patent law.

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